

REMARKS

Reconsideration of this Application is respectfully requested. Applicants wish to thank the Examiner for your kind consideration during the Examiner Interview conducted on March 9, 2009. Further arguments and comments of Applicants are set forth herein. Claims 1, 2 and 12 are amended and Claim 11 is cancelled, collectively, without prejudice or disclaimer. Claims 1-10 and 12 are in this case.

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First, the Examiner has again rejected Claims 2 and 11 under 35 U.S.C. § 112, Second Paragraph, for indefiniteness. Specifically, she maintains her position that Applicants' purported use of relative terminology in referencing an object that is variable (i.e., the specific weight of internal organs, blood or other fluid) renders the Claims indefinite. Notably, during the Examiner Interview on March 9th, the Examiner commented further that Applicants' use of the term "specific weight" adds nothing to the Claims, and recommended that the term be removed as, in her view, it was inherent that the object would have to float.

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In response, Applicants respectfully maintain their disagreement with the Examiner's assertion that the terminology used, with reference to internal organs, blood or other body fluids, is improper. However, given the Examiner's official notation during the Examiner Interview that the term "specific weight" adds nothing to the Claims, and that floatation of Applicants' feature is inherent, such language has been deleted from Claims 2 and 11, without prejudice or disclaimer.

Withdrawal of the Examiner's rejections under § 112, Second Paragraph, is appropriate.

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The Examiner also repeated her rejection of Claims 10 and 11 under 35 U.S.C. § 102(b) as allegedly anticipated by Yoon, U.S. Patent No. 6,248,088. According to the Examiner, with respect to Claim 10, Yoon discloses an organic fluid absorbing plug 16 for surgical use. Such plug, says the Examiner, comprises an elongated body constructed of a material having haemostatic properties. She also asserts that Yoon discloses the body connected to a radio-opaque locator 22. This time, however, the Examiner provides further explanation, namely, clarifying her belief that the body is capable of floating relative to internal organs, blood, or other fluids present at the surgical site, and that both the body and the locator are generally simultaneously delivered to, and recovered from, the surgical site. As to Claim 11, the Examiner repeats her finding that the alleged locator 22 of Yoon comprises at least one ball and is connected to the plug by a wire (the Examiner referring to FIG. 7).

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Thereafter, the Examiner reiterated her rejection of Claims 1-9 under 35 U.S.C. § 103(a) as obvious and, thus, unpatentable over Yoon in view of Reynolds et al., U.S. Patent No. 6,673,080. The Examiner asserts, with respect to Claim 1, that Yoon discloses a surgical device for removing organic fluids from a body cavity. The device, the Examiner continues, comprises an absorbing plug 16, a tubular body 28 suitable for slidably housing the plug, and a plunger 30 slidably engageable in the tubular body so as to push the plug outside thereof and place it at the surgical site (the Examiner again

citing to column 4, lines 49-60). In addition, the Examiner finds that the tubular body and plunger of Yoon have a distal end and a proximal end, wherein the plug is connected to a radio-opaque locator 22. This time, however, the Examiner comments, in addition, that such locator is capable of floating relative to internal organs, blood or other fluids present at the surgical site.

While the Examiner argues further that Yoon discloses removal of the plug, she admits that this reference fails to teach Applicants' "method and means" of removal (making reference to column 3, lines 52-54). The Examiner also indicates that Yoon fails to disclose that, at the distal end of the plunger, a handle is provided for gripping the locator to recover the plug after use by retracting the plunger inside the tubular body. The Examiner then looks to the teachings of Reynolds et al. which, she says, disclose providing a handle 30 for gripping and recovering material by retracting a plunger inside a tubular body (the Examiner referring to FIG. 1 and column 2, lines 30-35).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to have provided a handle, as allegedly taught by Reynolds et al., in the device of Yoon to provide a means for removing the plug from the body.

With reference to Claim 2, the Examiner takes the position that the alleged locator 22 of Yoon comprises at least one ball and is connected to the plug by a wire (purportedly in FIG. 7). As to Claim 3, although the Examiner acknowledges that Yoon does not disclose the size of the locator relative to the tube, she asserts that Yoon (column 4, lines 28-30) does teach successively inserting the plug through a tubular body. Accordingly, the Examiner decides that it would have been obvious to one of ordinary skill in the art to have made the locator smaller than the inner dimensions of the

tubular body, this time the Examiner stating, such that the locator may pass through the tubular body to allow for easier sequential insertion of the plugs.

Referring now to Claims 4 and 5, the Examiner admits that Yoon fails to disclose a loop at the distal end of the plunger. She then looks to Reynolds et al. as purportedly teaching that it is well-known in the art to retrieve material from within the body using a loop at the end of a plunger to grasp and retract the material so that it may be extracted from the body. The Examiner also argues that Reynolds et al. disclose the loop formed by a relatively thin plate bent and connected at its ends to the distal end of the stem of the plunger (FIG. 1). She concludes that it would have been obvious to one of ordinary skill in the art to have provided a loop for grasping the locator, as allegedly suggested by Reynolds et al., because, she says, such is a well-known structure used to retrieve foreign objects from the body. In addition, the Examiner finds that it would have been obvious to make the loop generally wider than the locator so that the loop would fit around the ball. Otherwise, says the Examiner, the loop could not function to retrieve the plug.

With respect to Claim 6, the Examiner repeats her argument that Reynolds et al. provide, at the proximal end of the tubular body and of the stem, a handle for actuating axial sliding of the stem in one direction or the other as a result of corresponding pressure actions exerted simultaneously in opposite directions on the handle (the Examiner making reference to Reynolds et al. - FIG. 1 and column 6, lines 21-35). Reynolds et al., the Examiner explains further, additionally discloses a handle of a ring type for allowing engagement with the fingers of a user (citing FIG. 1), as allegedly set forth by Applicants' Claim 7.

The Examiner further argues, with regard to Applicants' Claim 8, that Reynolds et al. teach a pair of handle rings at the proximal end of a tubular body, and generally diametrically opposite to and coplanar with one another, and at the proximal end of the stem, a handle ring generally coplanar thereto (the Examiner making reference to FIG. 1).

Moreover, the Examiner takes the position that Yoon discloses that the plug is preferably white in color to provide contrast with surrounding tissue (referencing column 5, lines 5-7), but acknowledges that this reference fails to teach the color of the locator surface. The Examiner reasons, however, that it would have been obvious to one of ordinary skill in the art to have also made the locator white or a relatively light color to provide contrast with the surrounding tissue and fluids, as purportedly suggested by Yoon.

The Examiner then rejected Claim 12 under 35 U.S.C. § 103(a) as obvious and, therefore, unpatentable over Yoon. According to the Examiner, Yoon discloses that the plug is preferably white in color to provide contrast with the surrounding tissue (allegedly at column 5, lines 5-7, in particular), while admitting that Yoon fails to describe the color of the locator or "ball" surface. Yet, she determines that it would have been obvious to one of ordinary skill in the art to have also made the locator white, or colored with a relatively light color, to provide contrast with the surrounding tissue and fluids, as allegedly suggested by Yoon.

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Finally, in response to Applicants' arguments, as set forth in their Amendment dated July 30, 2008, the Examiner states, with regard to Applicant's alleged arguments

regarding her rejection of Claims 2 and 11 under § 112, Second Paragraph, that she maintains this rejection because the large range of densities of internal organs, blood, and particularly “other fluids” each vary not only within a patient but also widely from one size of patient to another.

Second, in response to Applicant’s purported argument that tag 22 of Yoon must be larger than the cross section of the tube, the Examiner insists that there is nothing disclosed in the Specification, with respect to the size of the tag, to indicate that the tag must absolutely be too large to fit through the tube. Furthermore, she says, the tag is disclosed as being radiopaque which would be unnecessary if the tag was always externally located. On this basis, the Examiner concludes that Yoon does not disclose a reason to discourage one skilled in the art from modifying the locator to fit through the tube.

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Indeed, at the kernel of the Examiner’s rejection in this case is a misreading and complete misapplication of the teachings of Yoon, U.S. Patent No. 5,074,840.

As a preliminary matter, Applicants respectfully state that an Examiner’s citation and application of references must be based on what is reasonably set forth in the references. Rejections may *not* be based on an Examiner’s speculation or even her “best guess” as to what is purportedly shown and described in any reference. Simply stated, the teachings of the references are the teachings of the references, and the facts are the facts. It is not within the purview of the Examiner to bend or manipulate the teachings to suit a particular argument as to what factually is not of record.

In the case at hand, we submit, the Examiner is not only manufacturing disclosure that simply is *not* supported by any of the references, but she is also basing her rejection on conjecture and guesses about what the device of Yoon may (or may not) even do.

Hence, from the outset, we respectfully submit that the Examiner's analysis is contrary to the facts.

First, tag 22, as specifically defined by Yoon, is an identification tag that, in fact, serves as a way to identify a specific absorbing plug when it has to be extracted from the body cavity. Applicants cite, in this regard, to Column 4, lines 36-45 of Yoon.

Second, as clearly set forth in the embodiment of Yoon's FIG. 7, identification tag 22 *must* remain completely outside the body cavity and is *not* intended for recovery of the plug. As described at Column 5, lines 27-39 of Yoon, identification tag 22 has an "inlet" for connection to a source of suction to drain the liquid absorbed by the internal plug. Indeed, we submit, if identification tag 22 was intended by Yoon to enter the body cavity, then it would no longer be connected to the suction source. In other words, identification tag 22 *must* remain on the outside of the body cavity so that the specific plug to be drained can be identified - in case more than one plug is currently operative in the body cavity. It is obvious, we respectfully submit, that identification tag 22 teaches away from Applicants' invention.

Third, in *each and every one* of Yoon's drawings, wire 20 - which connects the plug to identification tag 22 - is *always* shown in broken line format. This demonstrates *unequivocally* that the length of the wire utilized by Yoon is considerably longer than what is shown in the drawings, and is contrary to the very short wire length provided by Applicants' invention which is part and parcel to its operation.

The foregoing is best described in the Specification from after the fourth full paragraph on page 6 to before the first full paragraph on page 7, as follows:

Once the plug has served its function, it must be recovered and removed from the abdominal cavity. To this end, as shown in FIGS. 4a, 4b and 4c, initially ball 10 is identified visually. Eyelet end 4a of the stem is then moved toward the ball such that it passes suitably through the loop and hooks wire 9 of the plug. Next, through light hand movements of the surgeon, the loop is caused to slide along the wire, pulling the stem backward, generally in the direction of arrow F in FIG. 4c, until the plug has returned to a position completely inside the tubular sheath. Thereafter, the device is disengaged from the trocar.

Indeed, the wire disclosed by Yoon is much too long to be used effectively for the purpose suggested by the Examiner. Logically and inherently, if Yoon's wire was intended to be short - like Applicants' wire - and, in turn, have the same function as well, then it would be shown and described as such.

Fourth, naming item 22 an "identification tag" simply does not disclose, imply, nor does it suggest a three-dimensional ball shape, according to Applicants' invention, but only a round flat shape. In fact, in *each and every one* of Yoon's drawings, identification tag 22 is *always* shown with shading that *expressly and unequivocally* illustrates a flat surface area. Again, the Examiner's argument, in this regard, falls short of the facts.

Fifth, in reply to the Examiner's insistence that there is nothing disclosed in the Specification, with respect to the size of identification tag 22, to indicate that the tag must absolutely be too large to fit through the tube, the Examiner assumes that not only the plugs, but also the relevant tags, are inserted sequentially in the body cavity; whereas such is neither disclosed nor suggested by Yoon. Indeed, we respectfully submit, a lower

size of the alleged ball relative to the tube would be obvious *only* if Yoon's identification tag 22 was intended to be passed through the tube.

The Examiner's assertion that the radiopaque nature of identification tag 22 would be unnecessary if the tag was always externally located is similarly without basis in fact or in law, as is the Examiner's conclusion that Yoon does not disclose a reason to discourage one skilled in the art from modifying the locator to fit through the tube. Indeed, use of radiopaque materials outside the body is known in the art, as demonstrated by Yoon. Notwithstanding, the operative legal analysis is motivation to combine, not discouragement.

Sixth, although the Examiner argues that it would have been obvious, in view of Reynolds et al., to provide a loop at the end of a material retrieving device, according to Applicants' Claims 4 and 5, Reynolds et al. disclose a basket, not a loop.

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We respectfully submit, the endoscopic device of Applicants' invention novelly incorporates both a plug delivering device and a plug recovering device in a single instrument, which integrated combination is neither disclosed nor suggested by any of the references cited.

Again, although the Examiner argues that identification tag 22 of Yoon corresponds to locator 10 of Applicants' invention, tag 22 does not disclose nor does it suggest locating and recovering a plug in and from, respectively, a body cavity. To the contrary, tag 22 must be *larger* than the tube cross section and serves *only* to prevent the plug from escaping from the tube. Unlike Applicants' invention, this arrangement makes the plug's recovery both complicated and difficult.

This, we submit, is completely contrary to the locator ball of Applicants' invention which must pass *through* the tube to reach the body cavity together with the plug.

Moreover, Applicants' invention utilizes a ball, that is, locator 10, rather than a flat disk, i.e., tag 22 of Yoon. The advantages offered by Applicants' ball-shaped locator are considerable, especially the combination of its novel shape with a specific gravity that is lower than that of the surrounding fluid at the surgical site, allowing it to "float" rather than sink into the patient's blood, tissues or bodily tissues. This is distinct and different from the teachings of Yoon whose *only* requirement for the disk shaped tag is that it be larger than the tube in order to avoid entering the same.

Furthermore, Yoon does not teach a locator designed to be dispensed, together with the plug, at the surgical site. Yoon, in addition, neither discloses nor does he suggest, nor would his teachings induce one skilled in the art to combine his plug with a basket device, as purportedly taught by Reynolds et al. This is because the plug of Yoon may *not* be separated from the endoscope. Hence, there is no need for a device that recovers the plug as the plug is simply retracted by grasping a tag to pull a cable to which the plug is attached.

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Applicant respectfully submits that none of the cited references, whether taken alone or in any combination, disclose or suggest Applicant's invention, as claimed. Withdrawal of the Examiner's rejections under §§ 112, Second Paragraph, 102(b) and 103(a) is, therefore, respectfully requested.

The Specification, Claims and Abstract are amended to further comport with U.S. practice and, in so doing, to better define the invention without limiting effect, for clarity, consistency, and as a matter of desired style.

Applicant has made a good faith attempt to place this Application in condition for allowance. Favorable action is requested. If there is any further point requiring attention prior to allowance, the Examiner is asked to contact Applicants' counsel at (646) 265-1468.


Respectfully submitted,

Dated: March 12, 2009

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